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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/084,471	05/22/1998	PATRICIA D. MURPHY	5371.31.US02	5585
9629	7590	10/05/2004	EXAMINER	
MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004			MYERS, CARLA J	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 10/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/084,471

Applicant(s)

MURPHY ET AL.

Examiner

Carla Myers

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 61-84 and 87-101 is/are pending in the application.
- 4a) Of the above claim(s) 62-84 and 87-94 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 61 and 95-101 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/1/01.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☒ Other: FASTDB sequence comparisons (2 sheets)

DETAILED ACTION

1. This action is in response to the amendment filed July 8, 2004. Applicants arguments and amendments have been fully considered but are not persuasive to overcome all grounds of rejection. All rejections/objections not reiterated herein are hereby withdrawn. This action is made final.

Election/Restrictions

2. Claims 62-84 and 87-94, as well as the subject matter of claim 61(b), are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the response of October 22, 2001. In this response, Applicants elected the invention of claim 61(a), nucleic acids comprising a BRCA2 gene containing a thymidine at a position in exon 15 corresponding to nucleotide 171 of SEQ ID NO: 2.

Claims 85 and 86 have been cancelled. Claims 61 and newly added claims 95-101 have been examined herein. Claims 62-84 and 87-94 are withdrawn from consideration.

Claim Objections

3. Claim 96 is objected to because of the following informalities:

In claim 96, "nucleic acid molecule of of claim 61" should read "nucleic acid molecule of claim 61."

Claim Rejections - 35 USC § 112

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4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 61 and 95-101 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 61 and 95-101 are indefinite over the recitation of “corresponding” because this is not an art recognized term and the specification does not provide a clear definition for this term. It is not clear if “corresponding” refers to the identical nucleotide position, a complementary nucleotide position or a nearby nucleotide position. Additionally, the claims do not clearly define the variation with respect to the overall BRCA2 gene. That is, defining the sequence variation with respect to a position in SEQ ID NO: 2 does not clearly define the variation with respect to the claimed nucleic acid comprising the BRCA2 gene. The claims should be amended to clarify the location of the variation with respect to exon 15 and the BRCA2 gene.

It is noted that in the response filed July 8, 2004, Applicants did not specifically address this rejection. Accordingly, the rejection is maintained for the reasons stated above.

THE FOLLOWING CONSTITUTE NEW GROUNDS OF REJECTION NECESSITATED BY APPLICANTS AMENDMENTS TO THE CLAIMS:

B. Claims 61 and 95-101 are indefinite and confusing because the claim recites the language of “selected from the group consisting of,” however, the claim does not recite a group. Rather, the claim recites only a single nucleotide variation. This rejection

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may be overcome by amendment of the claims to recite, for example, "containing a nucleotide variation wherein the nucleotide variation is a thymidine at a position..."

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 61 and 95-101 are rejected under 35 U.S.C. 102(b) as being anticipated by Holt (U.S. Patent No. 5,891,857; cited in the IDS).

Holt teaches isolated BRCA2 nucleic acids having a T at a nucleotide position which corresponds to position 199 of SEQ ID NO: 2 (see sequence comparison printout of present SEQ ID NO: 2 and SEQ ID NO: 3 of Holt - particularly position 7804 in SEQ ID NO: 3 of Holt). The recitation in the claims of "a thymidine at a position in exon 15 corresponding to nucleotide 199 of SEQ ID NO: 2" does not clarify the position of the thymine relative to the full length nucleic acid that is claimed. Since Holt teaches a sequence in which there is a T at a position that corresponds to position 199 of SEQ ID NO: 2, Holt is considered to teach the claimed nucleic acids. Further, Holt (see, for example, column 5) teaches cloning the BRCA2 gene into a vector and transforming host cells with vectors containing the BRCA2 gene. Holt also teaches methods of making recombinant BRCA2 proteins wherein the methods comprise transforming host cells with vectors comprising the BRCA2 nucleic acid of SEQ ID NO: 3 and fragments

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thereof and synthesizing BRCA2 proteins. Accordingly, Holt anticipates the claimed invention.

6. Claims 61 and 95-101 are rejected under 35 U.S.C. 102(a) as being anticipated by Futreal (U.S. Patent No. 6,045,997; cited in the IDS).

Futreal teaches isolated BRCA2 nucleic acids having a T at a nucleotide position which corresponds to position 199 of SEQ ID NO: 2 (see sequence comparison printout of present SEQ ID NO: 2 and SEQ ID NO: 1 of Futreal - particularly position 1399 in SEQ ID NO: 1 of Futreal). The recitation in the claims of "a thymidine at a position in exon 15 corresponding to nucleotide 199 of SEQ ID NO: 2" does not clarify the position of the thymine relative to the full length nucleic acid that is claimed. Since Futreal teaches a sequence in which there is a T at a position that corresponds to position 199 of SEQ ID NO: 2, Futreal is considered to teach the claimed nucleic acids. Further, Futreal (see, for example, column 11) teaches cloning the BRCA2 gene into a vector and transforming host cells with vectors containing the BRCA2 gene. Futreal also teaches methods of making recombinant BRCA2 proteins wherein the methods comprise transforming host cells with vectors comprising the BRCA2 nucleic acid of SEQ ID NO: 3 and fragments thereof and synthesizing BRCA2 proteins. Accordingly, Futreal anticipates the claimed invention.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571)-272-0782.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

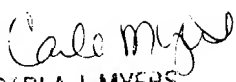
For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Application/Control Number: 09/084,471

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Carla Myers
September 22, 2004


CARLA J. MYERS
PRIMARY EXAMINER


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FEATURE:
NAME/KEY: CDS
LOCATION: 79..242
US-08-755-587-31

Query Match      97.8%; Score 213.2; DB 3; Length 722;
Best Local Similarity 98.6%; Pred. No. 5.1e-60;
Matches 215; Conservative 0; Mismatches 3; Indels 0; Gaps 0;

QY 1 TTTTCTAAGTATTTTCTTTGATAGATTTTAAATTACAGTCTTCAGAAATGCCAGAGAT 60
DB 49 TTTTCTAAGTATTTTCTTTGATAGATTTTAAATTACAGTCTTCAGAAATGCCAGAGAT 108
QY 61 ATACAGATATGCAATTAAAGAAAGAAACAAAGGCAACGGCTCTTTCCACAGCCAGGCGAGT 120
DB 109 ATACAGATATGCAATTAAAGAAAGAAACAAAGGCAACGGCTCTTTCCACAGCCAGGCGAGT 168
QY 121 CTGTATCTTGCAGAAATCATCCACTCTGCGCTCGAATCTCTCTGAAAGCAGCTGTAGGAGGC 180
DB 169 CTGTATCTTGCAGAAATCATCCACTCTGCGCTCGAATCTCTCTGAAAGCAGCTGTAGGAGGC 228
QY 181 CAAGTTCCCTCTGCGTGTCTCATAAACAGGTATGTGT 218
DB 229 CAAGTTCCCTCTGCGTGTCTCATAAACAGGTATGTGT 266

RESULT 2
US-08-755-587-1
; Sequence 1, Application US/08755587
; Patent No. 6045997
; GENERAL INFORMATION:
; APPLICANT: Futreal, Phillip A
; APPLICANT: Wooster, Richard F
; APPLICANT: Ashworth, Alan
; APPLICANT: Stratton, Michael R
; TITLE OF INVENTION: Materials and methods relating to the
; TITLE OF INVENTION: identification and sequencing of the BRCA2 cancer
; NUMBER OF SEQUENCES: 222
; CORRESPONDENCE ADDRESS:
; ADDRESSEE: Bell Seltzer Park & Gibson
; STREET: 310 UCB Plaza, 3605 Glenwood Avenue, PO Drawer 31107
; CITY: Raleigh
; STATE: NC
; COUNTRY: USA
; COMPUTER READABLE FORM:
; MEDIUM TYPE: Floppy disk
; COMPUTER: IBM PC compatible
; OPERATING SYSTEM: PC-DOS/MS-DOS
; SOFTWARE: Patent In Release #1.0, Version #1.25 (EPO)
; CURRENT APPLICATION DATA:
; APPLICATION NUMBER: US/08/755,587
; FILING DATE: 25-NOV-1996
; PRIOR APPLICATION DATA:
; APPLICATION NUMBER: GB 9523959.6
; FILING DATE: 23-NOV-1995
; PRIOR APPLICATION DATA:
; APPLICATION NUMBER: GB 9525555.0
; FILING DATE: 14-DEC-1995
; APPLICATION NUMBER: GB 9617961.9
; FILING DATE: 28-AUG-1996
; ATTORNEY/AGENT INFORMATION:
; NAME: Kenneth D Sibley
; REGISTRATION NUMBER: 31,665
; REFERENCE/DOCKET NUMBER: 5405-135
; INFORMATION FOR SEQ ID NO: 1:
; SEQUENCE CHARACTERISTICS:
; LENGTH: 1917 base pairs
; TYPE: nucleic acid
; STRANDEDNESS: single
; TOPOLOGY: linear
; MOLECULE TYPE: cdna
US-08-755-587-15

Query Match      84.7%; Score 184.6; DB 3; Length 7240;
Best Local Similarity 97.9%; Pred. No. 1.6e-50;
Matches 187; Conservative 0; Mismatches 4; Indels 0; Gaps 0;

QY 26 TAGATTTAATTACAGTCTTCAGAAATGCCAGAGATATACAGATATGCAATTAAGAAGA 85
DB 1226 TAGATTTAATTACAGTCTTCAGAAATGCCAGAGATATACAGATATGCAATTAAGAAGA 1285
QY 86 AACAAAGCGCAACGGCTCTTTCCACAGCCAGGCTCTCTATCTTCCAAAACATCCACTC 145
DB 1286 AACAAAGCGCAACGGCTCTTTCCACAGCCAGGCTCTCTATCTTCCAAAACATCCACTC 1345
QY 146 TGCCTCGAATCTCTCTGAAAGCAGCTGTAGGAGGCCAAAGTTCCCTCTGCGTGTCTCAT 205
DB 1346 TGCCTCGAATCTCTCTGAAAGCAGCTGTAGGAGGCCAAAGTTCCCTCTGCGTGTCTCAT 1405
QY 206 AACAGGTATGT 216
DB 1406 AACAGCTGTAT 1416

RESULT 3
US-08-755-587-15
; Sequence 15, Application US/08755587
; Patent No. 6045997
; GENERAL INFORMATION:
; APPLICANT: Futreal, Phillip A
; APPLICANT: Wooster, Richard F
; APPLICANT: Ashworth, Alan
; APPLICANT: Stratton, Michael R
; TITLE OF INVENTION: Materials and methods relating to the
; TITLE OF INVENTION: identification and sequencing of the BRCA2 cancer
; NUMBER OF SEQUENCES: 222
; CORRESPONDENCE ADDRESS:
; ADDRESSEE: Bell Seltzer Park & Gibson
; STREET: 310 UCB Plaza, 3605 Glenwood Avenue, PO Drawer 31107
; CITY: Raleigh
; STATE: NC
; COUNTRY: USA
; COMPUTER READABLE FORM:
; MEDIUM TYPE: Floppy disk
; COMPUTER: IBM PC compatible
; OPERATING SYSTEM: PC-DOS/MS-DOS
; SOFTWARE: Patent In Release #1.0, Version #1.25 (EPO)
; CURRENT APPLICATION DATA:
; APPLICATION NUMBER: US/08/755,587
; FILING DATE: 25-NOV-1996
; PRIOR APPLICATION DATA:
; APPLICATION NUMBER: GB 9523959.6
; FILING DATE: 23-NOV-1995
; PRIOR APPLICATION DATA:
; APPLICATION NUMBER: GB 9525555.0
; FILING DATE: 14-DEC-1995
; APPLICATION NUMBER: GB 9617961.9
; FILING DATE: 28-AUG-1996
; ATTORNEY/AGENT INFORMATION:
; NAME: Kenneth D Sibley
; REGISTRATION NUMBER: 31,665
; REFERENCE/DOCKET NUMBER: 5405-135
; INFORMATION FOR SEQ ID NO: 15:
; SEQUENCE CHARACTERISTICS:
; LENGTH: 7240 base pairs
; TYPE: nucleic acid
; STRANDEDNESS: single
; TOPOLOGY: linear
; MOLECULE TYPE: cdna
US-08-755-587-15
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